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TRANSMITTAL FORM <i>(to be used for all correspondence after initial filing)</i>		Application Number	09/406,473
		Filing Date	September 27, 1999
		First Named Inventor	Stephen D. Pacetti
		Group Art Unit	3763
		Examiner Name	Loan H. Thanh
Total Number of Pages in This Submission	20	Attorney Docket Number	50623.00008

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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT	
Firm or Individual name	Squire, Sanders & Dempsey L.L.P. Mark Lupkowski, Ph.D., Reg. No. 48,010
Signature	
Date	June 7, 2007

CERTIFICATE OF MAILING			
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Application No. 09/406,473
Appeal Brief
June 7, 2007



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Stephen D. Pacetti	Examiner: Loan H. Thanh
Serial No. 09/406,473	Art Unit: 3763
Filed: September 27, 1999	
Title: Drug Diffusion Barriers For A Catheter Assembly	

Mail Stop Appeal Brief-Patents

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**RESPONSE TO NOTIFICATION OF NON-COMPLIANT
APPEAL BRIEF**

Sir:

In response to the Notification of Non-Compliant Appeal Brief mailed May 7, 2007, Applicant respectfully requests entry of the attached Amended Appeal Brief and this Response into the record.

I. Amendments

Applicant has amended the Appeal Brief to remove the reference in the Evidence Appendix, and to add a Related Proceedings Appendix. Additionally, references to the Evidence Appendix on page 4 have been amended.

Attached is an Amended Appeal Brief incorporating all of the above amendments. Applicant has also attached a marked up version of the pages that were amended.

Application No. 09/406,473
Appeal Brief
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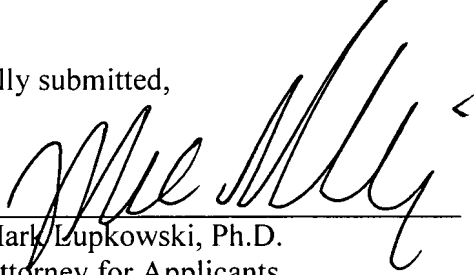
II. Conclusion

Applicant still asserts that the rejection of Claims 142, 143, and 147 as being unpatentable under 35 U.S.C. 103 over Sanhatjian is in error, and the Board is respectfully requested to reverse the rejection.

Respectfully submitted,

Date: June 7, 2007

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor Application of: Stephen D. Pacetti	Examiner: Loan H. Thanh
Serial No. 09/406,473	Art Unit: 3763
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Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

AMENDED APPEAL BRIEF

Sir:

On December 4, 2006, applicant appealed to the Board of Patent Appeals from the nonfinal rejection of Claims 139-154 which have been twice rejected. The following is applicant's Appeal Brief submitted pursuant to 37 C.F.R. §41.37.

Real Party in Interest

This application is assigned to Advanced Cardiovascular Systems, Inc. which is now Abbott Vascular, a division of Abbott of Abbott Park, Illinois, which is the real party in interest in this appeal.

Related Appeals and Interferences

Applicant and his counsel are not aware of any related appeals or interferences which would affect, be affected by, or have a bearing on the instant appeal.

Status of Claims

Claims 139-154 are pending and have been twice rejected by the Examiner. Claims 142, 143, and 147 form the subject of this appeal.

Claims 1-138 have been canceled.

Status of Amendments

There are no unentered amendments.

Summary of Claimed Subject Matter

The pending claims include one independent claim: Claim 139.

Applicant's invention recited in independent claim 139 is directed to a sheath (22) comprising a hollow body, the sheath (22) being adapted to removably cover at least part of an implantable medical object (12 and 16) that carries a therapeutic substance, wherein the sheath material prevents the therapeutic substance from significantly absorbing into the sheath (22) (Figure 1 and the specification, page 6, line 26 to page 8, line 17), wherein the sheath material has an oxygen transmission rate of not more than 200 cc/100 in² for 1 mil per 24 hours at 73°F, 75% relative humidity and 1 atmosphere, and wherein the sheath material has a water vapor transmission rate of not more than 20 gm/100 in² for 1 mil per 24 hrs. 100°F 90% relative humidity and 1 atm (specification, page 9, lines 16-20). As recited in dependent Claim 140, the implantable object (12 and 16) is a balloon (16) integrated with a catheter (12) (specification, page 7, line 8). Claim 141 recites that the balloon material, sheath material, or both comprise the same or different polymeric material (specification, page 9, lines 13-15). Claim 142 recites that the polymeric material comprises a polyurethane having a glass transition temperature above a storage temperature (specification, page 10, lines 23-24). Claim 143 recites that the polymeric material comprises a polyurethane having a non-polar soft segment wherein the non-polar soft segment is selected from hydrocarbons, silicones, fluorosilicones, or their mixtures (specification, page 10, lines 25-27).

Grounds of Rejection to Be Reviewed on Appeal

Issue 1: Whether Claim 142 is obvious over Sanhatjian et al. (U.S. Patent 5,674,192) ("Sanhatjian") under 35 U.S.C. § 103.

Issue 2: Whether Claim 143 is obvious over Sanhatjian under 35 U.S.C. § 103.

Issue 3: Whether Claim 147 is obvious over Sanhatjian under 35 U.S.C. § 103.

Argument

Issue 1

The Examiner has rejected Claim 142 as being obvious over Sanhatjian. The rejection is improper because the cited art does not disclose at least the following limitation of Claim 142: “the polymeric material comprises a polyurethane having a glass transition temperature above a storage temperature” and because there is no motivation or suggestion in the record to modify the cited art to include the limitation.

The record shows that the Examiner takes the position (Office Action mailed September 7, 2006 and Office Actions going back to October 5, 2004) that it is inherent that the polyurethane has a glass transition temperature (T_g) that is above the storage temperature. The inherency theory is based on two grounds: (1) that it is inherent that the polyurethane of Sanhatjian has a glass transition temperature (T_g) that is above storage temperature because the storage temperature can be “any temperature” and (2) it would be inherent “for the T_g to be above storage temperature since the sheath would be a solid structure” and that “if the T_g were below the storage temperature then the sheath would be a liquid or unstable form during storage.” These two grounds are without merit.

With respect to the first ground of inherency, the Examiner asserts that “in the broadest interpretation the storage temperature can be any temperature.” The Examiner’s interpretation of the “storage temperature can be any temperature” is entirely inconsistent with the MPEP and with Federal Circuit Case law. The MPEP § 2111 directs the Examiner to give the claims their broadest reasonable interpretation consistent with the specification. MPEP § 2111 also states that “the broadest reasonable interpretation of the claims must also be consistent with the interpretation that those skilled in the art would reach.” In re Cortright, 165 F.3d 1353, 1359 (Fed. Cir. 1999) Therefore, the Examiner must view the claim terms through the eyes of a skilled artisan and consider the specification. Applicant submits that a skilled artisan knows how to pick reasonable storage temperatures for medical devices based on the devices’ constituency and intended use.

Based on this correct interpretation of storage temperature, the limitation of Claim 142 is not inherent in Sanhatjian. Sanhatjian discloses a catheter comprising a sheath

extendable over a balloon to inhibit release of drug from a coating over an expandable portion of the catheter. (Col. 3, lines 23-25, Sanhatjian) Furthermore, it is disclosed that the sheath can be made of polyurethane (for example, Tecoflex™) or TEFLON (fluorinated polymer). (Col. 6, lines 62-63, Sanhatjian) As noted in the response filed January 5, 2005, it is established in the art, for instance *An investigation of the Fatigue Induced Failure Modes of Fiber/Elastomer Composites as Bearing Surfaces in Total Hip Joint Prosthesis*, published by the National Textile Center in its 1997 Annual report, that a medical grade Tecoflex™ has a Tg as low as -69.10, which is well below a reasonable storage temperature.

According to MPEP § 2112, inherency may not be established by probabilities or possibilities.” (quoting In re Robertson, 169 F.3d 743, 745, 49 USPQ2d.1949, 1950-51 (Fed. Cir. 1999). “In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teaching of the applied prior art.” MPEP § 2112 (quoting Ex Parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990)).

Since the allegedly inherent characteristic must flow from the prior art teaching, even a single example on the record contrary to the Examiner’s inherency theory precludes finding that a characteristic is inherent in the prior art. Thus, since extrinsic evidence in the above-mentioned article shows that the Tg of polyurethane is not necessarily above a reasonable storage temperature, Claim 142 is not inherent.

With respect to the Examiner’s second ground of inherency, the record shows that the Examiner makes certain factual assumptions in the Office Action mailed September 7, 2006: (1) the sheath must remain a solid to function; and (2) that if Tg is below a storage temperature, the material will either not be a solid or will be unstable. While the sheath’s function may require that the sheath remain a solid, nothing in its function requires that the sheath remain rigid. Thus, there is nothing in the record to support (2). A Tg below a storage temperature is perfectly compatible with the object being a solid. Tg is not a melting temperature of a polymer. Tg is the point at which the polymer begins the transition from behaving in a crystalline manner to behaving in an elastomeric manner. The transition from crystalline to elastomeric occurs over a broad temperature range wherein Tg is somewhat arbitrarily placed.

Many polymers have a Tg below room temperature or a reasonable storage temperature, yet they remain solids. These facts are well known to a person of skill in the art. Medical polymers such as Tecoflex™ and common rubbers have a Tg below room temperature and body temperature and yet remain solid above their respective Tg's. If they did not, such polymers would not be used in medical applications or automobile tires under conditions above their respective Tg's. In addition, a Tg below a storage temperature is perfectly compatible with an object being stable. Tecoflex™ and rubber would not be used for medical applications and tires, respectively, at temperatures above their respective Tg's if they were unstable at these temperatures. Thus, since extrinsic evidence shows that a polymer with a Tg below a storage temperature can be a solid or stable, it is not inherent that the polyurethane has a Tg that is above storage temperature.

Furthermore, the record shows that the Examiner takes the position that skilled artisans would immediately recognize that properties such as flexibility and bendability (properties indicative of a material tending to be above its Tg) are useful in the medical arts (Office Action mailed September 7, 2006, page 6, lines 4-6), but also takes the position that keeping the polymeric material solid, with the material's storage temperature below Tg, is inherent in prior art polymers. These two positions are diametrically opposed.

Applicant has established that the recited limitations of Claim 142 are not inherent. Furthermore, the Examiner has provided no motivation or suggestion for modifying Sanhatjian to have the limitations of Claim 142. The records shows that the Examiner (Office Action mailed September 7, 2006 and previous Office Actions) also rely on In re Leshin to supply Sanhatjian's deficiency with regard to applicant's claimed polyurethane. Reliance on In Re Leshin with respect to claim 142 is not appropriate. In Leshin, the material in question, plastic, was selected for use in the claimed device based on its known suitability for the applicant's intended purpose. Only the applicants have recognized the suitability of polyurethane having a glass transition temperature above a storage temperature of a sheath material. No prior art cited in the record provides any sort of recognition that applicant's claimed polymer would be suitable as a sheath material.

Applicant submits that the rejection of Claim 142 under 35 U.S.C. § 103 is in error and respectfully request that the rejection be reversed.

Issue 2

The Examiner has rejected Claim 143 as being obvious over Sanhatjian. The rejection is improper because the cited art does not disclose at least the following limitation of Claim 143: “the polymeric material comprises a polyurethane having a non-polar soft segment wherein the non-polar soft segment is selected from hydrocarbons, silicones, fluorosilicones, or their mixtures” and because there is no motivation or suggestion in the record to modify the cited art to include the limitation.

The record shows that the Examiner acknowledges (Office action mailed September 7, 2006) that Sanhatjian does not disclose the above-mentioned limitation of Claim 143. However, the Examiner asserts that “it is common knowledge in the chemical art to modify the non-polar segments in order to provide properties such as flexibility and bendability which are desired in the medical arts” and concludes that “it would have been obvious to modify any medically acceptable material to the essential properties, which are desired.” These assertions in the record are without merit for the following reasons.

The Examiner is required to identify the differences between the invention as claimed and then reason why one of ordinary skill in the art would modify the prior art to get to applicant’s claimed invention. Graham v. John Deere Co., 383 U.S. 1, 17-18 (1965) While skilled artisans know to modify polymers to change their properties, obviousness in this case requires them to know which modifications to make and by how much. This remains beyond the capacity of skilled artisans. With respect to the capacity of skilled artisans, the Examiner is making factual assumptions which is the same as taking official notice of those facts. Indeed, M.P.E.P. § 2144.03 states that “the rationale for supporting an obviousness rejection may be based on common knowledge in the art or ‘well-known’ prior art” and the “examiner may take official notice of facts outside of the record which are *capable of instant and unquestionable demonstration* as being ‘well-known’ in the art.”

The record does not contain any references showing that one of ordinary skill in the art, possessing the teachings of Sanhatjian, would immediately envision applicant’s claimed invention. Additionally, the record does not contain evidence that non-polar segments provide flexibility and bendability to polymers. The Response to Arguments section of the

Office Action mailed May 4, 2005 states in reference to applicant's claimed polymer "the material is known as the prior art shows the material used in the food industry." However, no specific material used in the food industry is cited. The record does not include a reference that discloses a polymeric material with "a polyurethane having a non-polar soft segment" in which "the non-polar soft segment is selected from hydrocarbons, silicones, fluorosilicones, or their mixtures."

To establish a *prima facie* case of obviousness, the Examiner is required to find some motivation or suggestion to make the claimed invention in light of the prior art teachings. MPEP 2143. Sanhatjian discloses the use of polyurethane and a commercial medical polyurethane, TecoflexTM (which does not have the above-mentioned claim limitations of Claim 143). However, there is no suggestion or motivation within Sanhatjian to use a polyurethane having the above-mentioned claim limitations of Claim 143. MPEP § 2144.08 (4) requires the Examiner to determine whether one of ordinary skill in the relevant art would have been motivated to make the claimed invention as a whole, i.e., to select the claimed species or subgenus from the disclosed prior art genus. Sanhatjian discloses the use of a genus, polyurethane, and a species, TecoflexTM, which does not have the limitations of Claim 143. There is no evidence in the record that one of ordinary skill in the art of polymers and medical devices would have been motivated to select a polymer having the limitations of Claim 143 for use in a sheath.

Many materials provide properties such as flexibility and bendability (such as TecoflexTM) other than the polyurethane recited by Claim 143. There is no motivation in the record to select applicant's claimed polyurethanes over many other polymers which could be selected that have bendability and flexibility. The motivation provided in the record that "it would have been obvious to modify any medically acceptable material to the essential properties" is merely an "obvious to try" rationale in support of an obviousness rejection. According to MPEP § 2145, "obvious to try" is not the standard under section 103.

In addition, the Office Action mailed September 7, 2006 relies on In re Leshin to supply Sanhatjian's deficiency with regard to applicant's claimed polyurethane. As discussed above, In Leshin, the material in question, plastic, was selected for use in the claimed device based on its known suitability for the applicant's intended purpose. Based on the record,

such is clearly not the case. Only the applicants have recognized the suitability of the claimed polyurethane as a sheath material. The only prior art cited in the record against claim 143 does not provide this recognition since the polyurethane disclosed by Sanhatjian is a different polymer with different properties. Other than applicant's specification and claims, there is nothing in the record concerning applicant's claimed polymer. Since there is nothing in the record about the claimed polymer, there is certainly nothing about its suitability for applicant's intended purpose.

Applicant submits that the rejection of Claim 143 under 35 U.S.C. § 103 is in error and respectfully request that the rejection be reversed.

Issue 3

The Examiner has rejected Claim 147 as being obvious over Sanhatjian. The rejections are improper because the cited art does not disclose at least the following limitation of Claim 147: "the balloon material, sheath material, or both comprise a therapeutic substance contacting surface" and because there is no motivation or suggestion in the record to modify the cited art to include the limitation.

Claim 147 depends from Claim 146 which recites "the balloon material, sheath material, or both comprise a therapeutic substance contacting surface." Claim 147 recites the limitation "the therapeutic substance contacting surface contacts a coating comprising a main-group-element oxide." Sanhatjian does not teach or suggest the limitations of Claim 147. The record does not provide a suggestion or motivation, either in a prior art reference or in the knowledge generally available to one of ordinary skill in the art, to supply Sanhatjian's deficiency with regard to the limitations of Claim 147. Therefore, a *prima facie* case of obviousness has not been made.

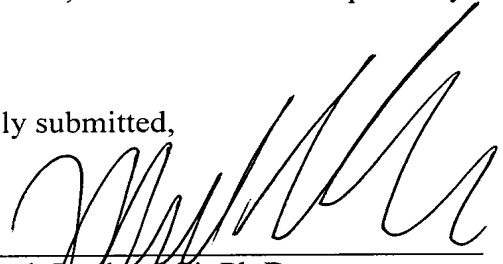
Applicant submits that the rejection of Claim 147 under 35 U.S.C. § 103 is in error and respectfully request that the rejection be reversed.

II. Conclusion

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For the foregoing reasons, the rejection of Claims 142, 143, and 147 as being unpatentable under 35 U.S.C. 103 over Sanhatjian is in error, and the Board is respectfully requested to reverse the rejection.

Respectfully submitted,



Date: June 7, 2007

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Claims Appendix

139. A sheath comprising a hollow body, the sheath being adapted to removably cover at least part of an implantable medical device that carries a therapeutic substance, wherein the sheath material prevents the therapeutic substance from significantly absorbing into the sheath, wherein the sheath material has an oxygen transmission rate of not more than 200 cc/100 in² for 1 mil per 24 hours at 73°F, 75% relative humidity and 1 atmosphere, and wherein the sheath material has a water vapor transmission rate of not more than 20 gm/100 in² for 1 mil per 24 hrs. 100°F 90% relative humidity and 1 atm.
140. The sheath of Claim 139 wherein the implantable object is a balloon integrated with a catheter.
141. The sheath of Claims 139-140 wherein the balloon material, sheath material, or both comprise the same or different polymeric material.
142. The sheath of Claim 141 wherein the polymeric material comprises a polyurethane having a glass transition temperature above a storage temperature.
143. The sheath of Claim 141 wherein the polymeric material comprises a polyurethane having a non-polar soft segment wherein the non-polar soft segment is selected from hydrocarbons, silicones, fluorosilicones, or their mixtures.
144. The sheath of Claim 141 wherein the implantable object comprises a stent.
145. The sheath of Claim 141 wherein the polymeric material comprises polyolefins, polyurethanes, derivatives of cellulose, polyesters, polyamides, poly(hexamethylene isophthalamide/terephthalamide), poly(ethylene terephthalate-co-p-oxybenzoate), poly(hydroxy amide ethers), polyacrylates, polyacrylonitrile, acrylonitrile/styrene copolymer, rubber-modified acrylonitrile/acrylate copolymer, poly(methyl methacrylate), liquid crystal polymers, poly(phenylene sulfide), polystyrenes, polycarbonates, poly(vinyl alcohols), poly(ethylene-vinyl alcohol), epoxies composed of bisphenol A based diepoxides with amine cure, aliphatic polyketones, polysulfones, poly(ester-sulfone), poly(urethane-sulfone), poly(carbonate-sulfone), poly(3-hydroxyoxetane), poly(amino ethers), gelatin, amylose, parylene-C, parylene-D, parylene-N, or their mixtures.

146. The sheath of Claim 141 wherein the balloon material, sheath material, or both comprise a therapeutic substance contacting surface.
147. The sheath of Claim 146 wherein the therapeutic substance contacting surface contacts a coating comprising a main-group-element oxide.
148. The sheath of Claim 147 wherein the main-group-element oxide comprises a silicon oxide, metal oxide, or a mixture of a silicon and a metal oxide.
149. The sheath of Claim 141 wherein the sheath material lines at least a portion of the inner surface of the sheath in a layer.
150. The sheath of Claim 149 wherein the implantable object is disposed within the sheath for transportation or storage.
151. The sheath of Claim 141 wherein the material is selected from:
 - polyurethane having a glass transition temperature above a storage temperature;
 - polyurethane having a non-polar soft segment wherein the non-polar soft segment is at least one of hydrocarbons, silicones, fluorosilicones, or mixtures thereof;
 - at least one cellulose derivative selected from cellulose acetate having a degree of substitution greater than about 0.8, ethyl cellulose, cellulose nitrate, cellulose acetate butyrate, methyl cellulose, or mixtures thereof;
 - sulfonated polymers;
 - fluorinated polymers;
 - carbide compounds;
 - nitride compounds;
 - a polyolefin that is at least one of polyethylenes, poly(vinyl chloride), poly(vinylidene chloride), poly(vinyl fluoride), poly(vinylidene fluoride), poly(tetrafluoroethylene), poly(chlorotrifluoroethylene), or mixtures thereof;
 - a polyester that is at least one of poly(ethylene terephthalate), poly(ethylene 2,6-naphthalene dicarboxylate), poly(butylene terephthalate), or mixtures thereof;

a polyamide that is at least one of nylon-6; nylon-6,6; nylon-6,9; nylon-6,10; aromatic nylon; or mixtures thereof; and

and any combinations thereof.

152. The method of Claim 151 wherein the polymeric material comprises a polyurethane having a glass transition temperature above a storage temperature.
153. The method of Claim 151 wherein the polymeric material comprises a polyurethane having a non-polar soft segment wherein the non-polar soft segment is selected from hydrocarbons, silicones, fluorosilicones, or their mixtures.
154. The method of Claim 151 wherein the implantable object comprises a stent.

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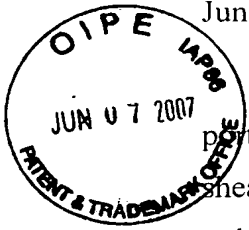
Evidence Appendix

NONE

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Related Proceedings Appendix

NONE



extendable over a balloon to inhibit release of drug from a coating over an expandable portion of the catheter. (Col. 3, lines 23-25, Sanhatjian) Furthermore, it is disclosed that the sheath can be made of polyurethane (for example, Tecoflex™) or TEFLON (fluorinated polymer). (Col. 6, lines 62-63, Sanhatjian) As noted in the response filed January 5, 2005, it is established in the art, for instance ~~The Evidence Appendix provides a copy of An investigation of the Fatigue Induced Failure Modes of Fiber/Elastomer Composites as Bearing Surfaces in Total Hip Joint Prosthesis~~, published by the National Textile Center in its 1997 Annual report, that. ~~This article was submitted with the response filed January 5, 2005 and shows the measurement of some Tecoflex™ polyurethanes. Reference to Table 1 of the Appendix shows that a medical grade Tecoflex™ has a Tg as low as -69.10, which is well below a reasonable storage temperature.~~

According to MPEP § 2112, inherency may not be established by probabilities or possibilities.” (quoting In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). “In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teaching of the applied prior art.” MPEP § 2112 (quoting Ex Parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990)).

Since the allegedly inherent characteristic must flow from the prior art teaching, even a single example on the record contrary to the Examiner’s inherency theory precludes finding that a characteristic is inherent in the prior art. Thus, since extrinsic evidence in the above-mentioned article shows that the Tg of polyurethane is not necessarily above a reasonable storage temperature, Claim 142 is not inherent.

With respect to the Examiner’s second ground of inherency, the record shows that the Examiner makes certain factual assumptions in the Office Action mailed September 7, 2006: (1) the sheath must remain a solid to function; and (2) that if Tg is below a storage temperature, the material will either not be a solid or will be unstable. While the sheath’s function may require that the sheath remain a solid, nothing in its function requires that the sheath remain rigid. Thus, there is nothing in the record to support (2). A Tg below a storage temperature is perfectly compatible with the object being a solid. Tg is not a melting temperature of a polymer. Tg is the point at which the polymer begins the transition from

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Evidence Appendix

NONE



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